COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24/01/2003
C(2003) 414

NOT FOR PUBLICATION

COMMISSION DECISION

of 24/01/2003

amending Decision C(2001)286 on the marketing authorization for the medicinal product for human use

"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

(Text with EEA relevance)

ONLY THE GERMAN TEXT IS AUTHENTIC.

COMMISSION DECISION

of 24/01/2003

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"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[3], as amended by Commission Regulation (EC) No 1069/98[4], and in particular Article 8(3) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase" entered in the Community register of medicinal products under Nos EU/1/00/168/001-006 authorised by Commission Decision C(2001)286 of 23 February 2001, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Boehringer Ingelheim International GmbH submitted an application on 28 June 2002 pursuant to Article 6(1) set out in Regulation (EC) No 542/95.

(3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 17 October 2002 by the Committee for Proprietary Medicinal Products,

[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ No L 55, 11.3.1995, p. 15
[4] OJ L 153, 27.5.1998, p. 11

(4) Decision C(2001)286 should therefore be amended accordingly.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2001)286 is amended as follows:

1. Annex I is replaced by Annex I to this Decision;

2. Annex III B is replaced by Annex II to this Decision.

Article 2

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 24/01/2003

For the Commission
Erkki LIIKANEN
Member of the Commission